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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/744,973	02/15/2001	Lily Bar	P66403US0	1395

136 7590 03/26/2003

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EXAMINER
GUPTA, ANISH

ART UNIT	PAPER NUMBER
1654	

DATE MAILED: 03/26/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/744,973	BAR ET AL.	
	Examiner	Art Unit	
	Anish Gupta	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-8 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-8 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

1. Claims 5 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 5, the method claims states that sucrose and glycine are added to yield a specific concentration. However, it is unclear what concentration is being adjusted. That is, is the addition of sucrose or glycine change the concentration the cryoprecipitate? Clarification is requested.

Claims 1-4 provides for the use of fibrinogen mulitmers, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claims 1-4 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunk*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

2. Claims 1-4 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The claims state that the fibrinogen has at least 6 fibrinogen units. The art indicates that naturally occurring fibrinogen is in the form of a hexamer that is composed of twoα, β, γ subunits (see col. 1, lines 19-25 in Grieninger et al). Since the claims do not recite isolated or purified, the claims read upon naturally occurring fibrinogen and thus are a product of nature. (Note that claims 1-4 have been treated as a product claim, rather than a method claim).

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1-6 are rejected under 35 U.S.C. 102(b) as being anticipated by Reis et al.

The claims are drawn to a fibrinogen mulitmers having at least 6 fibrinogen units.

The reference teaches a fibrin glue, a biological hemostatic adhesive, from fibrinogen (see page 473). The reference discloses the effects of sucrose and glycine as stabilizers for fibrinogen in a cryoprecipitate (see page 474). The method disclosed is the resuspension of cryoprecipitate and to it the addition of sucrose and glycine. Once glycine has been added, the solution is then heated for 10 hours at 60 degrees (see page 474). Finally, the solution is dialyzed. This method is the same method disclosed in the specification and claims. Thus, even though the reference does not

specifically state that multimeric fibrinogen was obtained, with at least six fibrinogen units, since the method is the same, the product would necessarily have been achieved.

Claim Rejections - 35 USC § 103

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103© and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. Claims 1-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Martinowitz et al. in view of Reis et al.

The claims are drawn to a fibrinogen mulitmers having at least 6 fibrinogen units.

Martinowitz et al. teaches a fibrin glue that comprises cryoprecipitate of whole blood and tranexamine acid (see page 4). The reference states commercially available cryoprecipitate can be

used in the preparation of the fibrin glue (see page 6). The presence of tranexamic acid results in the increase of efficiency of wound healing and increases the tensile strength of the fibrinogen. The difference between the prior art and the instant application is that the reference does not teach the method of obtaining a cryoprecipitate.

The reference of Reis et al. teach the effects of sucrose and glycine as stabilizers for fibrinogen in a cryoprecipitate (see page 474). The method disclosed is the resuspension of cryoprecipitate and to it the addition of sucrose and glycine. Once glycine has been added, the solution is then heated for 10 hours at 60 degrees (see page 474). The reference teach that the method disclosed protected fibrinogen in cryoprecipitate from inactivation by prolong exposure to heat during pasteurization. Thus, it would have been obvious to use the cryoprecipitate product of Reis et al. in Martinez because the presence of sucrose and glycine protected fibrinogen in cryoprecipitate from inactivation by prolong exposure to heat during pasteurization.

Since it would have been obvious to combine the cryoprecipitate product obtained in Reis et al. with Martinowitz et al. the fibrinogen product in the cryoprecipitate would necessarily have multimers greater than six fibrinogen units because the method of making and the active agents used would be identical to one another. Note that in the specification that the presence of tranexamic acid had an effect on the fibrinogen multimeric state. Thus the presence of tranexamic acid in composition of Martinowitz et al. would also lead to higher multimeric states.

6. Claims 1-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nur et al. in view of Reis et al.

The claims are drawn to a fibrinogen mulitmers having at least 6 fibrinogen units.

Martinowitz et al. teaches a fibrin glue that comprises cryoprecipitate of fibrinogen and tranexamine acid and arginine or lysine (see page 2-3). The reference states the fibrinogen comprising sample is derived from cryoprecipitate (see page 3). The presence of tranexamic acid and arginine stabilize a mixture containing fibrinogen (see page 4). The reference discloses that tranexamic acid is in concentration range of 5-15% and the arginine or lysine is in the range of 1-3% (see page 3). The difference between the prior art and the instant application is that the reference does not teach the method of obtaining a cryoprecipitate.

The reference of Reis et al. teach the effects of sucrose and glycine as stabilizers for fibrinogen in a cryoprecipitate (see page 474). The method disclosed is the resuspension of cryoprecipitate and to it the addition of sucrose and glycine. Once glycine has been added, the solution is then heated for 10 hours at 60 degrees (see page 474). The reference teach that the method disclosed protected fibrinogen in cryoprecipitate from inactivation by prolong exposure to heat during pasteurization. Thus, it would have been obvious to use the cryoprecipitate product of Reis et al. in Martinez because the presence of sucrose and glycine protected fibrinogen in cryoprecipitate from inactivation by prolong exposure to heat during pasteurization.

Since it would have been obvious to combine the cryoprecipitate product obtained in Reis et al. with Martinowitz et al. the fibrinogen product in the cryoprecipitate would necessarily have multimers greater than six fibrinogen units because the method of making and the active agents used would be identical to one another. Note that in the specification that the presence of tranexamic acid had an effect on the fibrinogen multimeric state. Thus the presence of tranexamic acid in composition of Martinowitz et al. would also lead to higher multimeric states.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anish Gupta whose telephone number is (703) 308-4001. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback , can normally be reached on (703)306-3220. The fax phone number of this group is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Anish Gupta

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